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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,105	07/15/2002	Terry Roemer	MK-05	5750

7590

03/07/2006

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EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,105

Applicant(s)

ROEMER ET AL.

Examiner

Michael D. Burkhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 5 is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt and entry of the amendment dated 12/6/2005 is acknowledged. After entry of the amendment, claims 1, 5, and 28-33 are pending and under examination.

#### *Priority*

In light of the PCT-903 (371 acceptance notice) form of record, the assertion in the previous Office Action that the instant application was not entitled to the claimed priority date of 5/05/199 was in error. The instant application is a 371 of PCT/CA00/00533, filed 5/05/2000, which claims benefit of 60/132,878, filed 5/5/1999. The instant application is granted a priority date of 5/5/1999.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 12/6/2005. This is a New Matter rejection.**

Applicants claim an isolated nucleic acid that hybridizes to a fragment of the nucleic acid molecule of claim 1 (represented by SEQ ID NO: 3) that encodes either amino acid positions 818-836 or 850-870 of SEQ ID NO: 4. Applicants point to page 7, line 28 through page 8, line 6, page 9, lines 24-27, page 12, lines 11-30, page 28, lines 12-19 and Fig. 2A as support for the claimed subject matter. The recited passages describe: what is intended by the term "fragments" (pages 7-8); that the present invention comprises nucleic acid molecules that hybridize to those disclosed in the instant specification, or fragments thereof (page 9); a description of nucleic acid hybridization and conditions thereof (page 12); the CaALR1 nucleotide and amino acid sequence (i.e. SEQ ID NOs 3 and 4, respectively), which comprises two putative transmembrane domains (page 28 and Fig. 2A). It is taken that the fragments recited in claim 29 (i.e. positions 818-836 or 850-870) are the transmembrane domains mentioned on page 28.

The instant claims recite nucleic acids that must encode specific portion(s) of the disclosed SEQ ID NO: 4. Nowhere in the above passages is found a specific reference or disclosure indicating Applicants considered the invention to be nucleic acids that encode such specific portions. Rather, broad, generic language is used, indicating that the invention may encompass "fragments" of the disclosed sequences. There is nothing in the specification to direct the skilled artisan to conclude that the instant invention included nucleic acids that encode the claimed specific portions of SEQ ID NO:4. Indeed, there is no specific disclosure, other than the full length SEQ ID NO: 3, of such nucleic acids. Therefore, there is no support for the limitation that the claimed polynucleotides encode amino acid positions 818-836 or 850-870 of SEQ ID NO: 4. Thus, the amended claims include impermissible New Matter.

Claim 33 is also considered to be new matter with regards to claim 1. The claim embraces detecting a nucleotide sequence encoding SEQ ID NO:4, which includes SEQ ID NO: 3 (and highly related sequences) but also includes nucleic acids with little sequence homology to SEQ ID NO:3. For example, due to the degeneracy of the genetic code, merely changing the wobble nucleotide in every codon (and for certain amino acids such as serine, leucine, and arginine, more than the wobble nucleotide can be changed) represents a nucleotide sequence with homology of less than 70% with SEQ ID NO: 3, but the nucleic acid would still encode SEQ ID NO: 4. There is no disclosure in the specification of nucleic acid probes that include this sequence degeneracy, nor of any sequences that they could detect using the claimed method (they would not detect SEQ ID NO: 3, for example). Thus, the amended claims include impermissible New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 12/6/2005.**

Claim 28 recites a nucleic acid comprising a nucleotide sequence that is at least 98% identical to SEQ ID NO: 3 and which is at least 2000 nucleotides in length. However, SEQ ID NO: 3 is 3,525 nucleotides in length. In order to be 98% identical to SEQ ID NO: 3, a nucleotide cannot be less than 3,456 nucleotides in length (i.e. a deletion of 2% of the nucleotide residues of

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SEQ ID NO: 3). Therefore it is unclear how the claimed nucleotides can be both 98% identical and be at least 2000 nucleotides in length (which represents only 56% identity to SEQ ID NO: 3).

### ***Conclusion***

Any rejection not repeated in this Office Action is withdrawn.

Claims 1 and 5 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

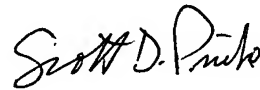
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart  
Examiner  
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A handwritten signature in black ink, reading "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER